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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,320	02/13/2001	Bernhard H. van Lengerich	BVL-102A	9819

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EXAMINER	
GRAFFEO, MICHEL	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 12/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/782,320	VAN LENGERICH, BERNHARD H.	
	Examiner	Art Unit	
	Michel Graffeo	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *See Continuation Sheet* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 25-31,34,35,37-40,42,46,50,52-59,61-67,69,70,73,75,79,81-85,91-93,95-97,101,103 and 105.

Continuation of Disposition of Claims: Claims rejected are 25-31,34,35,37-40,42,46,50,52-59,61-67,69,70,73,75,79,81-85,91-93,95-97,101,103 and 105.

DETAILED ACTION

Status of Action

Claims 25-31, 34-35, 37-40, 42, 46, 50, 52-59, 61-67, 69-70, 73, 75, 79, 81-85, 91-93, 95-97, 101, 103 and 105 are pending and examined.

Prosecution is re-opened. The Office apologizes for the previous Action dated 16 September 2004, but withdraws all indications of allowability of any of the instant claims. In light of the art cited below, this action is considered proper. Any rejection not specifically stated in this Office Action has been withdrawn.

The Election of Species provided in prior Responses dated 18 November 2002 and 14 November 2003 remain effective. To that end, the encapsulant elected is a liquid probiotic; the plasticized matrix material is starch/durum wheat; and the rate controlling component is fats and the claims considered readable thereon are noted above. If Applicant believes that claims should be added or removed from that list, Applicant is invited to make such a statement in its next response.

Claim Rejections - 35 USC § 112

Claims 25-31, 34-35, 37-40, 42, 46, 50, 52-59, 61-67, 69-70, 73, 75, 79, 81-85, 91-93, 95-97, 101, 103 and 105 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

To satisfy the written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that application was in possession of the claimed invention. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., Fujikawa v. Wattanasin, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) (a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species); In re Ruschig, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967).

Possession may be shown in many ways. For example, possession may be shown by describing an actual reduction to practice of the claimed invention. Possession may also be shown by a clear depiction of the invention in detailed drawings or in structural chemical formulas which permit a person skilled in the art to clearly recognize that applicant had possession of the claimed invention. An adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention. For example, a specification may describe an actual reduction to practice by showing that the inventor

constructed an embodiment or performed a process that met all the limitations of the claim and determined that the invention would work for its intended purpose or an applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole.

An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406.

A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. The disclosure of only one species

encompassed within a genus adequately describes a claim directed to that genus only if the disclosure "indicates that the patentee has invented species sufficient to constitute the gen[us]."

Applicant has not conveyed possession of the invention with reasonable clarity to one skilled in the art. The term probiotic is used only one time in the instant Specification and does not clearly convey to one of ordinary skill in the art the intended scope of the claim. A probiotic can include a microorganism or other nutrient to support the growth thereof[1].

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 25-31, 34-35, 37-40, 42, 46, 50, 52-59, 61-67, 69-70, 73, 75, 79, 81-85, 91-93, 95-97, 101, 103 and 105 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 4,187,321 to Mutai et al.

Mutai et al. teach a tablet or powder formulation (in current claims 25-31, 34-35, 37-40, 42, 46, 50, 52-59, 61-67, 69-70, 73, 75, 79, 81-85, 91-93, 95-97, 101, 103 and 105; see col 3 line 4) comprising a probiotic (Bifidobacterium and Lactobacillus

species), starch (in current claims 25-31, 34-35, 37-40, 42, 46, 50, 52-59, 61-67, 69-70, 73, 75, 79, 81-85, 91-93, 95-97, 101, 103 and 105; see col 5 Example 3) and fat (25-31, 34-35, 37-40, 42, 46, 50, 52-59, 61-67, 69-70, 73, 75, 79, 81-85, 91-93, 95-97, 101, 103 and 105; see col 2 lines 35-43) wherein the fat and probiotic can be combined and dried and further mixed with starch and further wherein the resulting product can be used in a food product (see col 2 lines 11-15).

Although Mutai et al. do not specifically recite the resultant amounts of probiotic and starch in the final product, Mutai et al. do approximate same (20 fold amount of starch leaves 5% for the dried milk/probiotic component) and one of ordinary skill in the art would have routinely optimized the amounts of each component based on the ultimate end use of the product and in light of the teachings in Mutai et al. in col 2 lines 35-40 which read that no "restriction is imposed on the composition of the media used for the mixed cultivation of obligatory anaerobic strains..." and further where Mutai et al. recite that no "restriction is placed on the means to process the culture or the type of final products as long as they do not kill the Bifidobacterium." (see col 3 lines 4-6).

Again Mutai et al. do not specifically recite the tablet dimensions, specific density of the product or release rates of the products. Nonetheless, since the products as claimed are the same as those in the art, the functional characteristics thereof must be the same. A product can not, absent evidence to the contrary, be separated from its characteristics particularly when it is used for the same purpose as that in the art. Dimensions of the tablet, on the other hand, are not material to patentability in that they

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[1] probiotic. Webster's New World™ Medical Dictionary (2003). Retrieved 07 December 2005, from xreferplus. http://www.xreferplus.com/entry/2438974

are routinely optimized by one of ordinary skill in the art and the tableting industry as a whole depending on target market for example. Again, Mutai et al. speaks to tablet size wherein it is recited that no "restriction is placed on the means to process the culture or the type of final products as long as they do not kill the Bifidobacterium." (see col 3 lines 4-6). Thus, the referenc teaches and makes prima facie obvious how to use the claimed invention at the time that it was made.

Response to Arguments

Applicant's arguments with respect to claims 25-31, 34-35, 37-40, 42, 46, 50, 52-59, 61-67, 69-70, 73, 75, 79, 81-85, 91-93, 95-97, 101, 103 and 105 have been considered but are moot in view of the new ground(s) of rejection.

Neither the IDS filed on or about 26 March 2001 nor the IDS filed on or about 8 March 2002 have a PTO-1449 attached. No IDS is present in the file having a filing date on or about 21 December 2001.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michel Graffeo whose telephone number is 571-272-8505. The examiner can normally be reached on 9am to 5:30pm Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

7 December 2005
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